K092723

OCT 4 2010

510(k) Summary of Safety and Effectiveness
Akro-Vu Videoscopic Carpal Tunnel Release System

May 5, 2010

Submitter:
Skeletal Dynamics, LLC
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FDA Establishment Registration Number: Pending

Trade Name, Common Name, Classification:
Device Trade Name: Akro-Vu Videoscopic Carpal Tunnel Release System
Akro-Vu
VCTRS

Device Common or Usual Names: Carpal Tunnel Release device, Arthroscope, Knives, Sheaths, Arthroscopic Cutting Instrument

Classification: Class II, 21 CFR 888.1100

Predicate Device:
Microaire CTRS / 3M Inside Job – K912871

Description of the Device:
The AKRO-VU Videoscopic Carpal Tunnel Release System (VCTRS) is designed as a stand-alone platform to address less invasive surgical approaches for Carpal Tunnel Release procedures performed by trained physicians. The AKRO-VU VCTRS is comprised of a reusable Video-Monitor with Li Ion Battery and Charger, an autoclavable Sterile Enclosure with Base Stand to house the Video-Monitor within the sterile field, an autoclavable Handle with cable assembly and Locking Ring, and two styles of single use disposable Video-Blades each containing a camera, light source and deployable blade. The AKRO-VU VCTRS is designed to be a battery powered system.

Intended Use:
The Akro-Vu Videoscopic Carpal Tunnel Release System (VCTR) is for use in patients diagnosed with carpal tunnel syndrome that is not associated with, or secondary to, any

other known pathology (i.e. idiopathic carpal tunnel syndrome). Preoperative x-rays of the wrist, including a carpal tunnel view, are recommended to aid in the diagnosis of associated pathology (i.e. calcific tendonitis, fracture of the hook of the hamate). This device is indicated solely for releasing the flexor retinaculum (transverse carpal ligament).

Contraindications
The device is not intended for use in patients with known abnormalities of their wrist (carpal tunnel), including distal radial deformities, rheumatoid and other synovitis.

Technological Characteristics:
The Akro-Vu Videoscopic Carpal Tunnel Release System has the following similarities to the Microaire CTRS manufactured and distributed by Microaire pursuant to K912871:

- The same indications for use and intended use
- The same basic general shape of the working instrument
- Utilize the same materials for the blade and the housing of the working instrument
- Use the same operating principals

Biocompatibility:
The materials selected for the Akro-Vu Videoscopic Carpal Tunnel Release System have a long history of safe use in the orthopedic industry. The materials include Stainless Steel, Ultem, Parylene, Polycarbonate, and Cyclo Olefin Polymer, and Silicone Rubber.

Summary:
The following safety and performance tests were performed in support of the submission:

- An assessment of the microbial barrier of the Sterile Enclosure was performed to evaluate the effectiveness of the barrier. The enclosure was found to be an effective microbial barrier.
- A comparative analysis of the blade (subject vs. predicate) was made to evaluate the edge radius for sharpness. The results indicate that both blades were comparable. Visualization testing was performed to test the video imaging capabilities of the system. The target image displayed was focused, illuminated and discernable within the specified ranges.
- A battery capacity test was performed to determine how long a fully charged battery would power the system. The system power on time exceeded the capacity requirement by a safety factor of 11.
- Temperature testing was done to determine the temperature at the distal end of the Videoblade at full power after 30 minutes of use. The temperature of the Videoblades tested after 30 minutes of use did not rise more than 1°C.
- A blade actuation test was performed to confirm the blade actuated after repeated actuations against a force. After cyclic testing, all test samples actuated smoothly throughout the entire range and the blade returned to a position sub-flush to the edge of the housing.

- Cut force testing was performed to confirm the cutting force of the Videoblade was within specified limits. The results indicated that the blades cut the test media within the required force parameters. Cadaveric evaluations of the blade were also performed to evaluate cut force on tissue. The blade was found to provide the necessary cut force on cadaver tissue.
- A series of strength tests were done to evaluate the Videoblade's ability to withstand typical loads during use. The test results concluded that all test samples met the stiffness and strength specifications for torsional, posterior cantilever, and lateral cantilever forces.

Conclusion:

Based on the performance testing and the comparative analyses, we believe the subject device performs as intended and is substantially equivalent to the predicate device. Therefore, we conclude that the subject device is safe and at least as effective as the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 4 2010

Skeletal Dynamics, LLC
% Orchid Design
Mr. Joseph M. Azary
80 Shelton Technology Center
Shelton, Connecticut 06484

Re: K092723
Trade/Device Name: Akro-Vu Videoscopic Carpal Tunnel Release System (VCTR)
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: September 17, 2010
Received: September 20, 2010

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson per DLC

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092723

Device Name: Akro-Vu Videoscopic Carpal Tunnel Release System (VCTR)

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092723